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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,612	05/14/2001	Thomas Spies	FHCC:003USC1	9260

7590 09/10/2002

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EXAMINER

DECLoux, AMY M.

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/855,612

Applicant(s)

SPIES ET AL.

Examiner

Amy M. DeCloux

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-101 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-101 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

It is noted that the instant claims contain claims numbered 1-72, 74-100 and 102-103. According to Rule 1.126, claims 74-100 have been renumbered as claims 73-99, and claims 102-103 have been renumbered 100-101. Applicant is required to make any necessary changes in claim dependencies.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-25, drawn to a method for detecting a cancer cell in a sample comprising identifying MICA or MICB expression, classified in class 435, subclass 7.2.
- II. Claims 26-45, drawn to a method for purifying V δ 1 γ δ T cells comprising contacting cells with MICA or MICB, classified in class 435, subclass 7.2.
- III. Claims 46-52, drawn to a method for enriching a cell population for V δ 1 γ δ T cells comprising contacting a cell population with MICA or MICB linked to a label, classified in class 435, subclass 7.2.
- IV. Claims 53-60, drawn to a method of targeting a therapeutic agent to a tumor cell expressing MICA or MICB on its surface comprising contacting said cell with a MICA or MICB binding agent, classified in class 435, subclass 7.2.
- V. Claims 61-72, drawn to a method of treating cancer comprising administering an agent conjugated to MICA or MICB, classified in class 424, subclass 184.1.
- VI. Claims 73-76, drawn to a method for expanding V δ 1 γ δ T cells in a T cell population comprising contacting said population with MICA or MICB, classified in class 435, subclass 7.2.
- VII. Claims 77-78, drawn to a method of immunotherapy comprising administering a purified population of V δ 1 γ δ T cells, classified in class 424, subclass 93.7.
- VIII. Claims 79-86, drawn to a method of increasing MICA expression in a cell comprising providing to a cell an expression construct comprising a coding region for MICA, classified in class 435, subclass 69.3.
- IX. Claims 87-92, drawn to a method of increasing MICB expression in a cell comprising an expression construct comprising a coding region for MICB, classified in class 435, subclass 69.3.

Art Unit: 1644

- X. Claims 93-96, drawn to a transgenic non-human mammal expressing a human MICA polypeptide, classified in class 800, subclass 14.
- XI. Claims 97-101, drawn to a transgenic non-human mammal expressing a human MICB polypeptide, classified in class 800, subclass 14.

The inventions are distinct, each from the other because of the following reasons:

Groups I-IX are unique methods. They differ with respect to their respective endpoints, and are therefore patentably distinct each from the other.

Groups X and XI are unique products because Group X encompasses a non human transgenic mammal expressing a human MICA polypeptide, while Group XI encompasses a non human transgenic mammal expressing a human MICB polypeptide, and as such Groups X and XI differ with respect to their biochemical makeup, and are therefore patentably distinct.

Groups X-XI and I-IX are unrelated products and methods and are therefore patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search in the non-patent literature of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

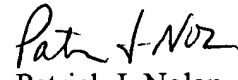
Application/Control Number: 09/855,612

Page 4

Art Unit: 1644

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner,
September 8, 2002


Patrick J. Nolan, Ph.D.,
Primary Patent Examiner,